

## IN THE CIRCUIT COURT OF MONTGOMERY COUNTY, ALABAMA

STATE OF ALABAMA,		
Plaintiff )	CV - 05-219	AN 30
ABBOTT LABORATORIES, et al.		PH 3:
Defendants )		23

# ANSWER OF DEFENDANT TAKEDA PHARMACEUTICALS NORTH AMERICA, INC. TO THE STATE OF ALABAMA'S SECOND AMENDED COMPLAINT

Defendant Takeda Pharmaceuticals North America, Inc. ("TPNA"), for its Answer to the State of Alabama's Second Amended Complaint ("Complaint") in the captioned action, by its undersigned counsel, alleges upon knowledge as to itself, and upon information and belief as to all other matters, as follows:

#### INTRODUCTION

- 1. The Defendants have engaged in false, misleading, wanton, unfair, and deceptive acts and practices in the pricing and marketing of their prescription drug products. The Defendants' fraudulent pricing and marketing of their prescription drugs have impacted elderly, disabled, and poor Alabama citizens covered by the State's Medicaid program ("Alabama Medicaid") by causing the Alabama Medicaid Agency to pay grossly excessive prices for the Defendants' prescription drugs.
- 1. TPNA denies each and every allegation set forth in paragraph 1 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 2. Fair and honest drug pricing is a matter of great importance to the State and its citizens. Expenditures by the State and its agencies for prescription drug reimbursement have increased dramatically in the past several years as a result, in part, of Defendants' fraudulent pricing scheme. Each year Alabama spends hundreds of millions of dollars on prescription drugs under the Alabama Medicaid program. In 2004 alone, Alabama Medicaid spent almost \$600 million on prescription drugs. Since 1990, Alabama

Medicaid prescription drug expenditures have increased tenfold. This exponential increase in prescription drug costs in recent years has contributed to a health care funding crisis within the State that requires action to ensure fair dealing between the Defendants and the State and its agencies.

- TPNA denies knowledge or information sufficient to form a belief as to the truth 2. of the allegations set forth in paragraph 2 of the Complaint, except TPNA denies the existence of a fraudulent pricing scheme, that TPNA is or has been involved in any such scheme, or that TPNA has not dealt fairly with the State and its agencies.
- The State is accountable to its citizens and taxpayers for how it spends 3. limited State resources, and it is obligated to pursue any party whose unlawful conduct has led to the overspending of State funds. Consequently, the State, by and through its Attorney General, brings this action to recover amounts overpaid for prescription drugs by Alabama Medicaid, including pharmacy dispensed drugs and co-payments for drugs covered by Medicare, as a result of the fraudulent and wanton conduct of Defendants. The State further seeks to prohibit and permanently enjoin Defendants from continuing to perpetrate their drug-pricing scheme, to require Defendants to publicly disclose true drug prices, and to require Defendants to account for and disgorge all profits obtained by Defendants as a result of their improper and unlawful actions.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 3. of the allegations set forth in paragraph 3 of the Complaint, except TPNA admits that the State of Alabama purports to bring this action, denies that there is any basis on which to permit the State to do so, denies that TPNA has engaged in any fraudulent and wanton conduct, denies the existence of any "drug pricing scheme," denies that TPNA is or has been involved in any such scheme, denies that TPNA has obtained any profits as a result of any such imagined scheme, and denies that TPNA has caused Alabama Medicaid to overpay for any drug sold by TPNA.
- This lawsuit seeks legal and equitable redress for the fraudulent and wanton marketing and pricing conduct of Defendants, who have profited from their wrongful acts and practices at the expense of the State.
- TPNA denies each and every allegation set forth in paragraph 4 of the Complaint 4. as to TPNA, except TPNA admits that the State of Alabama purports to seek legal and equitable redress but denies there is any basis on which to permit it to do so, and otherwise denies



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Defendant Takeda Pharmaceuticals North America, Inc. ("TPNA"), for its Answer to the State of Alabama's Second Amended Complaint ("Complaint") in the captioned action, by its undersigned counsel, alleges upon knowledge as to itself, and upon information and belief as to all other matters, as follows:

#### **INTRODUCTION**

- 1. The Defendants have engaged in false, misleading, wanton, unfair, and deceptive acts and practices in the pricing and marketing of their prescription drug products. The Defendants' fraudulent pricing and marketing of their prescription drugs have impacted elderly, disabled, and poor Alabama citizens covered by the State's Medicaid program ("Alabama Medicaid") by causing the Alabama Medicaid Agency to pay grossly excessive prices for the Defendants' prescription drugs.
- 1. TPNA denies each and every allegation set forth in paragraph 1 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 2. Fair and honest drug pricing is a matter of great importance to the State and its citizens. Expenditures by the State and its agencies for prescription drug reimbursement have increased dramatically in the past several years as a result, in part, of Defendants' fraudulent pricing scheme. Each year Alabama spends hundreds of millions of dollars on prescription drugs under the Alabama Medicaid program. In 2004 alone, Alabama Medicaid spent almost \$600 million on prescription drugs. Since 1990, Alabama

Medicaid prescription drug expenditures have increased tenfold. This exponential increase in prescription drug costs in recent years has contributed to a health care funding crisis within the State that requires action to ensure fair dealing between the Defendants and the State and its agencies.

- 2. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint, except TPNA denies the existence of a fraudulent pricing scheme, that TPNA is or has been involved in any such scheme, or that TPNA has not dealt fairly with the State and its agencies.
- 3. The State is accountable to its citizens and taxpayers for how it spends limited State resources, and it is obligated to pursue any party whose unlawful conduct has led to the overspending of State funds. Consequently, the State, by and through its Attorney General, brings this action to recover amounts overpaid for prescription drugs by Alabama Medicaid, including pharmacy dispensed drugs and co-payments for drugs covered by Medicare, as a result of the fraudulent and wanton conduct of Defendants. The State further seeks to prohibit and permanently enjoin Defendants from continuing to perpetrate their drug-pricing scheme, to require Defendants to publicly disclose true drug prices, and to require Defendants to account for and disgorge all profits obtained by Defendants as a result of their improper and unlawful actions.
- 3. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of the Complaint, except TPNA admits that the State of Alabama purports to bring this action, denies that there is any basis on which to permit the State to do so, denies that TPNA has engaged in any fraudulent and wanton conduct, denies the existence of any "drug pricing scheme," denies that TPNA is or has been involved in any such scheme, denies that TPNA has obtained any profits as a result of any such imagined scheme, and denies that TPNA has caused Alabama Medicaid to overpay for any drug sold by TPNA.
- 4. This lawsuit seeks legal and equitable redress for the fraudulent and wanton marketing and pricing conduct of Defendants, who have profited from their wrongful acts and practices at the expense of the State.
- 4. TPNA denies each and every allegation set forth in paragraph 4 of the Complaint as to TPNA, except TPNA admits that the State of Alabama purports to seek legal and equitable redress but denies there is any basis on which to permit it to do so, and otherwise denies

knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

#### **PARTIES**

- Plaintiff is the State of Alabama. The State brings this action in its capacity as sovereign and on behalf of the Alabama Medicaid Agency.
- TPNA admits that the State of Alabama purports to bring this action in its 5. capacity as sovereign and on behalf of the Alabama Medicaid Agency but denies that there is any basis on which to permit it to do so.
- The Attorney General, as chief law officer of the State of Alabama pursuant 6. to Alabama Code § 36-15-12, is statutorily authorized to initiate and maintain this action.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 6. of the allegations set forth in paragraph 6 of the Complaint and further respectfully refers the Court to Alabama Code § 36-15-12 for a full and complete reading of its provisions.

#### Defendant Abbott

- Defendant Abbott Laboratories, Inc. ("Abbott") is a Delaware corporation with its principal place or business located at 100 Abbott Park Road, Abbott Park, IL 60064. Ross Products is a division of Abbott. Abbott is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Abbott and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 7. of the allegations set forth in paragraph 7 of the Complaint.

#### Defendant Alcon

Defendant Alcon Laboratories, Inc.. ("Alcon") is a Delaware corporation 8. with its principal place of business located at 6201 S. Freeway (T1-3), Fort Worth, TX 76134-2099. Alcon is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Alcon and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.

TPNA denies knowledge or information sufficient to form a belief as to the truth 8. of the allegations set forth in paragraph 8 of the Complaint.

#### Defendant Allergan

- Defendant Allergan, Inc. ("Allergan") is a Delaware corporation with its 9. principal place of business located at 2525 Dupont Drive, Irvine, CA 92612. Allergan is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Allergan and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 9. of the allegations set forth in paragraph 9 of the Complaint.

#### The Alpharma Defendants

- Defendant Alpharma, Inc. ("Alpharma") is a Delaware corporation with its 10. principal place of business located at One Executive Drive, Fort Lee, NJ 07024-1399.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 10. of the allegations set forth in paragraph 10 of the Complaint.
- Defendant Purepac Pharmaceutical Co. ("Purepac"), a wholly-owned subsidiary of Alpharma, is a Delaware corporation with its principal place of business located at 14 Commerce Drive, Suite 301, Cranford, NJ 07016.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 11. of the allegations set forth in paragraph 11 of the Complaint.
- Alpharma and Purepac (collectively, the "Alpharma Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Alpharma Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 12. of the allegations set forth in paragraph 12 of the Complaint.

#### The Amgen Defendants

- 13. Defendant Amgen, Inc. ("Amgen") is a Delaware corporation with its principal place of business located at One Amgen Center Drive, Thousand Oaks, CA 91320-1799.
- 13. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 13 of the Complaint.
- 14. Defendant Immunex Corporation ("Immunex"), a Washington corporation with its principal place of business located at 51 University Street, Seattle, WA 98101, was acquired by Amgen in 2002.
- 14. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 14 of the Complaint.
- 15. Amgen and Immunex (collectively, the "Amgen Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Amgen Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 15. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 15 of the Complaint.

#### Defendant Andrx

- 16. Defendant Andrx Pharmaceuticals, Inc. ("Andrx Pharm") is a Florida corporation with its principal place of business located a 4955 Orange Drive, Davie, FL 33314. Andrx Pharm is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Andrx Pharm and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 16. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 16 of the Complaint.

#### The AstraZeneca Defendants

- 17. Defendant AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharm") is a Delaware limited partnership with its principal place of business located at 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850-5437.
- 17. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 17 of the Complaint.
- 18. Defendant AstraZeneca LP ("AstraZeneca"), formerly Astra Pharmaceuticals LP, is a Delaware limited partnership with its principal place of business located at 725 Chesterbrook Boulevard, Wayne, PA 19087.
- 18. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 18 of the Complaint.
- 19. AstraZeneca Pharm and AstraZeneca (collectively, the "AstraZeneca Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the AstraZeneca Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 19. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 19 of the Complaint.

#### The Aventis Defendants

- 20. Defendant Aventis Pharmaceuticals, Inc. ("Aventis") is a Delaware corporation with its principal place of business located at 300 Somerset Corporate Boulevard, Bridgewater, NJ 08807-2854.
- 20. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 20 of the Complaint.
- 21. Defendant Aventis Behring, L.L.C. ("Aventis Behring") is a Delaware limited liability company with its principal place of business located at 1020 First Avenue, King of Prussia, PA 19406-1310. Aventis Behring was formerly known as Centeon, L.L.C. and currently operates as ZLB Behring.

- 21. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 21 of the Complaint.
- 22. Defendant ZLB Behring, L.L.C. ("ZLB Behring"), formerly known as Aventis Behring, is a Delaware limited liability company and a subsidiary of CSL Limited of Melbourne Australia, with its principal place of business located at 1020 First Avenue, P.O. Box 61501, King of Prussia, PA 19406-0901.
- 22. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 22 of the Complaint.
- 23. Aventis, Aventis Behring, and ZLB Behring (collectively, the "Aventis Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Aventis Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 23. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 23 of the Complaint.

#### Defendant Barr

- 24. Defendant Barr Laboratories, Inc. ("Barr"), a subsidiary of Barr Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 2 Quaker Road, P.O. Box 2900, Pomona, NY 10970-0519. Barr is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Barr and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 24. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 24 of the Complaint.

#### The Baxter Defendants

25. Defendant Baxter International, Inc. ("Baxter International") is a Delaware corporation with its principal place of business located at One Baxter Parkway, Deerfield, IL 60015-4633.

- 25. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 25 of the Complaint.
- 26. Defendant Baxter Healthcare Corporation ("Baxter Healthcare"), a wholly-owned subsidiary of Baxter International, Inc., is a Delaware corporation with its principal place of business located at One Baxter Parkway, Deerfield, IL 60015.
- 26. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 26 of the Complaint.
- Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Baxter Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 27. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 27 of the Complaint.

#### The Bayer Defendants

- 28. Defendant Bayer Corporation ("Bayer"), formerly Miles, Inc., is an Indiana corporation with its principal place of business located at 100 Bayer Road, Pittsburgh, PA 15205-9707. Bayer Corporation is a wholly-owned United States subsidiary of Bayer AG, a German corporation with its principal place of business located at 51368 Leverkusen, Germany.
- 28. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 28 of the Complaint.
- 29. Defendant Bayer Pharmaceuticals Corporation ("Bayer Pharm") is a Delaware corporation with its principal place of business located at 400 Morgan Lane, West Hayen, CT 06516.
- 29. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 29 of the Complaint.
- 30. Defendant Bayer Healthcare, LLC ("Bayer Healthcare") is a legally independent company with six divisions operating under the Bayer AG umbrella. Bayer

Healthcare is a Delaware limited liability company with its principal place of business located at 511 Benedict Avenue, Tarrytown, NY 10591.

- TPNA denies knowledge or information sufficient to form a belief as to the truth 30. of the allegations set forth in paragraph 30 of the Complaint.
- Bayer, Bayer Pharm, and Bayer Healthcare (collectively, the "Bayer 31. Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs and biological products that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals and biological products that are manufactured, distributed, marketed, and/or sold by the Bayer Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 31. of the allegations set forth in paragraph 31 of the Complaint.

### Defendant Biovail

- Defendant Biovail Pharmaceuticals, Inc. ("Biovail") is a Delaware 32. corporation with its principal place of business located at 700 Route 202206, North Bridgewater, NJ 08807. Biovail is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Biovail and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 32. of the allegations set forth in paragraph 32 of the Complaint.

## The Boehringer Defendants

- Defendant Boehringer Ingelheim Corporation ("Boehringer") is a Nevada 33. corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, CT 06877. Boehringer includes a number of subsidiary companies that manufacture, distribute, market, and/or sell prescription drugs, including, but not limited to, the following:
  - Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer a. Pharm") is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, CT 06877; and

- b. Defendant Roxane Laboratories, Inc ("Roxane"), a Delaware corporation with its principal place of business located at 1809 Wilson Road, Columbus, OH 43228-9579.
- 33. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 33 and lettered subparagraphs a and b of the Complaint.
- Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Boehringer Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 34. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 34 of the Complaint.

## Defendant Bristol-Myers Squibb

- 35. Defendant Bristol-Myers Squibb Company ("Bristol-Myers Squibb"), formerly Bristol-Myers Company, is a Delaware corporation with its principal place of business located at 345 Park Avenue, New York, NY 10154-0037. Bristol-Myers Squibb, which includes a number of divisions and/or subsidiary companies, is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Bristol-Myers Squibb, and/or its subsidiaries and divisions, and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 35. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 35 of the Complaint.

#### Defendant DEY

36. Defendant DEY, L.P. ("DEY"), formerly DEY Laboratories, is a Delaware limited partnership with its principal place of business located at 2751 Napa Valley Corporate Drive, Napa, CA 94558. DEY is an indirect subsidiary of Merck KGaA, a German pharmaceutical conglomerate, and is an affiliate of EMD, Inc. DEY is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by DEY and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.

36. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 36 of the Complaint.

#### Defendant Eisai

- 37. Defendant Eisai, Inc. ("Eisai"), the U.S. pharmaceutical subsidiary of Tokyobased Eisai Co., Ltd., is a Delaware corporation with its principal place of business located at 500 Frank W. Burr Boulevard, Teaneck, NJ 07666. Eisai is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Eisai and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 37. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 37 of the Complaint.

#### Defendant Endo

- 38. Defendant Endo Pharmaceuticals, Inc. ("Endo"), formerly Endo Laboratories, L.L.C., and a subsidiary of Endo Pharmaceuticals Holdings, Inc., is a Delaware corporation with its principal place of business located at 100 Painters Drive, Chadds Ford, PA 19317. Endo is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Endo and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 38. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 38 of the Complaint.

#### Defendant ETHEX

- 39. Defendant ETHEX Corporation ("ETHEX"), a wholly-owned subsidiary of K-V Pharmaceutical Company, is a Missouri corporation with its principal place of business at 10888 Metro Court, St. Louis, MO 63043-2413. ETHEX is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are sold by ETHEX and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 39. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 39 of the Complaint.

#### The Forest Defendants

- 40. Defendant Forest Laboratories, Inc. ("Forest") is a Delaware corporation with its principal place of business located at 909 Third Avenue, New York, NY 10022.
- 40. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 40 of the Complaint.
- 41. Defendant Forest Pharmaceuticals, Inc. ("Forest Pharm"), a wholly-owned subsidiary of Forest, is a Delaware corporation with its principal place of business located at 13600 Shoreline Drive, St. Louis, MO 63045.
- 41. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 41 of the Complaint.
- 42. Forest and Forest Pharm (collectively, the "Forest Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, marketing, distributing, and/or selling prescription drugs that are reimbursed by State Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Forest Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 42. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 42 of the Complaint.

## The Fujisawa Defendants

- 43. Defendant Fujisawa Healthcare, Inc. ("Fujisawa") is a Delaware corporation and a wholly-owned subsidiary of Fujisawa Pharmaceutical Company, Ltd., of Osaka, Japan. Fujisawa's principal place of business is located at Three Parkway North, Deerfield, IL 60015.
- 43. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 43 of the Complaint.
- 44. Defendant Fujisawa USA, Inc. ("Fujisawa USA") is or was a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, IL 60015.
- 44. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 44 of the Complaint.

- 45. Fujisawa and Fujisawa USA (collectively, the "Fujisawa Defendants") are or were engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are or were manufactured, distributed, marketed, and/or sold by the Fujisawa Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 45. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 45 of the Complaint.

## Defendant Genzyme

- 46. Defendant Genzyme Corporation ("Genzyme"), formerly Genzyme Massachusetts Corporation, is a Massachusetts corporation with its principal place of business located at 500 Kendall Street, Cambridge, MA 02139. Genzyme is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Genzyme and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 46. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 46 of the Complaint.

## Defendant Gilead

- 47. Defendant Gilead Sciences, Inc. ("Gilead") is a Delaware corporation with its principal place of business located at 333 Lakeside Drive, Foster City, CA 94404. Gilead is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Gilead and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 47. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 47 of the Complaint.

#### Defendant GlaxoSmithKline

48. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GlaxoSmithKline"), is a Pennsylvania corporation with its principal place of business located at One Franklin Plaza, 200 North 16<sup>th</sup> Street, Philadelphia, PA 19102. GlaxoSmithKline is engaged in the business of manufacturing, distributing, marketing, and/or and selling prescription drugs that are reimbursed by state Medicaid agencies

nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by GlaxoSmithKline and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.

48. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 48 of the Complaint.

#### The Hoffmann-LaRoche Defendants

- 49. Defendant Hoffmann-LaRoche, Inc. ("Hoffmann-LaRoche") is a New Jersey corporation with its principal place of business located at 340 Kingsland Street, Nutley, NJ 07110-1199. Hoffmann-LaRoche is the U.S. prescription drug unit of the Roche Group.
- 49. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 49 of the Complaint.
- 50. Defendant Roche Laboratories, Inc. ("Roche Labs") is a Delaware corporation with its principal place of business located at 340 Kingsland Street, Nutley, NJ 07110-1199. Roche Labs is a marketing and sales subsidiary of Hoffmann-LaRoche.
- 50. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 50 of the Complaint.
- Defendants") are diversified healthcare companies that individually, and/or in combination with one another; engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Hoffmann-LaRoche Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 51. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 51 of the Complaint.

#### The IVAX Defendants

- 52. Defendant IVAX Corporation ("IVAX") is a Florida corporation with its principal place of business located at 4400 Biscayne Blvd., Miami, FL 33137-3227.
- 52. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 52 of the Complaint.

- 53. Defendant IVAX Pharmaceuticals, Inc ("IVAX Pharm"), a wholly-owned subsidiary of IVAX, is a Florida corporation with its principal place of business located at 4400 Biscayne Blvd., Miami, FL 33137.
- 53. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 53 of the Complaint.
- 54. IVAX and IVAX Pharm (collectively, the "IVAX Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the IVAX Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 54. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 54 of the Complaint.

## The J&J Defendants

- 55. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. J&J includes a number of subsidiary or affiliate companies including, but not limited to, the following:
  - a. Defendant ALZA Corporation ("ALZA"), is a Delaware corporation with its principal place of business located at 1900 Charleston Road, Mountain View, CA 94039, and was acquired by J&J from Defendant Abbott in 2000;
  - b. Defendant Janssen Pharmaceutical Products, LP ("Janssen"), a wholly-owned subsidiary of J&J, is a New Jersey limited partnership with its principal place of business located at 1125 Trenton-Harbourton Road, Titusville, NJ 08560;
  - c. Defendant McNeil-PPC, Inc. ("McNeil"), a wholly-owned subsidiary of J&J, is a New Jersey corporation with its principal place of business located at 7050 Camp Hill Road, Fort Washington, PA 19034. McNeil Consumer & Specialty Pharmaceuticals ("McNeil Cons") is a division of McNeil-PPC, Inc.;
  - d. Defendant Ortho Biotech Products, LP ("Ortho Biotech"), a wholly-owned subsidiary of J&J, is a New Jersey limited partnership with its principal place of business located at 430 Rt. 22 East, Bridgewater, NJ 08807-0914; and

- e. Defendant Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"), a wholly-owned subsidiary of J&J, is a Delaware corporation with its principal place of business located at 1000 U.S. Route 202 South, Raritan, NJ 08869.
- 55. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 55 and lettered subparagraphs a through e of the Complaint.
- 56. J&J, ALZA, Janssen, McNeil, Ortho Biotech, and Ortho-McNeil (collectively "the J&J Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the J&J Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 56. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 56 of the Complaint.

## The King Defendants

- 57. Defendant King Pharmaceuticals, Inc. ("King") is a Tennessee corporation with its principal place of business located at 501 Fifth Street, Bristol, TN 37620.
- 57. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 57 of the Complaint.
- 58. Defendant Monarch Pharmaceuticals, Inc. ("Monarch"), a wholly-owned subsidiary of King, is a Tennessee corporation with its principal place of business located at 501 Fifth Street, Bristol, TN 37620.
- 58. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 58 of the Complaint.
- 59. King and Monarch (collectively, the "King Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the King Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.

59. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 59 of the Complaint.

#### Defendant MedImmune

- 60. Defendant MedImmune, Inc. ("MedImmune") is a Delaware corporation with its principal place of business located at One MedImmune Way, Gaithersburg, MD 20878. MedImmune is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by MedImmune and reimbursed by Alabama Medicaid fur which a claim is made in this litigation are identified in Exhibit A, attached.
- 60. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 60 of the Complaint.

#### Defendant Merck

- 61. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation with its principal place of business located at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100. Merck is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Merck and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 61. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 61 of the Complaint.

#### The Mylan Defendants

- 62. Defendant Mylan Laboratories, Inc. ("Mylan") is a Pennsylvania corporation with its principal place of business located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.
- 62. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 62 of the Complaint.
- 63. Defendant Mylan Pharmaceuticals, Inc ("Mylan Pharm"), a wholly-owned subsidiary of Mylan, is a West Virginia corporation with its principal place of business located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

- 63. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 63 of the Complaint.
- 64. Defendant UDL Laboratories, Inc. ("UDL"), a wholly-owned subsidiary of Mylan, is an Illinois corporation with its principal place of business located at 1718 Northrock Court, Rockford, IL 61103.
- 64. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 64 of the Complaint.
- 65. Mylan, Mylan Pharm, and UDL (collectively, the "Mylan Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Mylan Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 65. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 65 of the Complaint.

## The Novartis Defendants

- 66. Defendant Novartis Pharmaceuticals Corporation ("Novartis") is a Delaware corporation with its principal place of business located at One Health Plaza, East Hanover, NJ 07936-1080.
- 66. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 66 of the Complaint.
- 67. Defendant Sandoz, Inc ("Sandoz"), formerly known as Geneva Pharmaceuticals, Inc., and a member of the Novartis group of companies, is a Delaware corporation with its principal place of business located at 506 Carnegie Center, Suite 400, Princeton, NJ 08540-6243.
- 67. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 67 of the Complaint.
- 68. Novartis and Sandoz (collectively, the "Novartis Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are

manufactured, distributed, marketed, and/or sold by the Novartis Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.

68. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 68 of the Complaint.

#### Defendant Novo Nordisk

- 69. Defendant Novo Nordisk Pharmaceuticals, Inc. ("Novo Nordisk") is a Delaware corporation with its principal place of business located at 100 College Road West, Princeton, NJ 08540-7814. Novo Nordisk is the U.S. health care affiliate of Novo Nordisk A/S. Novo Nordisk is engaged in the business of manufacturing, distributing, marketing, and/or selling pharmaceuticals that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Novo Nordisk and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 69. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 69 of the Complaint.

## **Defendant Organon**

- 70. Defendant Organon Pharmaceuticals USA, Inc. ("Organon"), a subsidiary of Akzo Nobel NV, is a Delaware corporation with its principal place of business located at 56 Livingston Avenue, Roseland, NJ 07068. Organon is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Organon and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 70. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 70 of the Complaint.

#### Defendant Par

71. Defendant Par Pharmaceutical, Inc. ("Par") is a New Jersey corporation with its principal place of business located at One Ram Ridge Road, Spring Valley, NY 10977. Par is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Par and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.

71. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 71 of the Complaint.

#### The Pfizer Defendants

- 72. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, NY 10017. With the merger of Pfizer and Pharmacia Corporation in 2003, Pfizer became the largest drug company in the world today.
- 72. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 72 of the Complaint.
- 73. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its principal place of business located at 235 East 42<sup>nd</sup> Street, New York, NY 10017-5755.
- 73. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 73 of the Complaint.
- 74. Defendant Pharmacia & Upjohn Company Corporation ("P & U"), a subsidiary of Pharmacia Corporation, is a Delaware corporation with its principal place of business located at 235 E. 42<sup>nd</sup> Street, New York, NY 10017-5703.
- 74. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 74 of the Complaint.
- 75. Defendant G.D. Searle, L.L.C. ("Searle"), a subsidiary of Pharmacia Corporation, is a Delaware limited liability company with its principal place of business located at 4901 Searle Parkway, Skokie, IL 60077-2919.
- 75. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 75 of the Complaint.
- 76. Defendant Agouron Pharmaceuticals, Inc, ("Agouron") is a California corporation with its principal place of business located at 10777 Science Center Drive, San Diego, CA 92121.
- 76. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 76 of the Complaint.

- Pfizer, Pharmacia, P & U, Searle and Agouron (collectively, the "Pfizer Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Pfizer Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 77. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 77 of the Complaint.

#### Defendant Purdue

- 78. Defendant Purdue Pharma, L.P. ("Purdue") is a Delaware limited partnership with its principal place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Purdue and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 78. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 78 of the Complaint.

#### Defendant Sanofi

- 79. Defendant Sanofi-Synthelabo, Inc. ("Sanofi"), the U.S. affiliate of the global pharmaceutical company Sanofi-Aventis, is a Delaware corporation with its principal place of business located at 90 Park Avenue, New York, NY 10016. Sanofi is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Sanofi and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 79. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 79 of the Complaint.

#### The Schering Defendants

80. Defendant Schering-Plough Corporation ("Schering-Plough") is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, NJ 07033.

- 80. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 80 of the Complaint.
- 81. Defendant Warrick Pharmaceuticals Corporation ("Warrick"), a wholly-owned subsidiary of Schering-Plough, is a Delaware corporation with its principal place of business located at 12125 Moya Blvd., Reno, NV 89506-2600.
- 81. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 81 of the Complaint.
- 82. Schering-Plough and Warrick (collectively, the "Schering Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Schering Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 82. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 82 of the Complaint.

## **Defendant TAP Pharmaceutical**

- 83. Defendant TAP Pharmaceutical Products, Inc. ("TAP"), a joint venture between Abbott Laboratories and Takeda Chemical Industries, Ltd., of Osaka, Japan, is a Delaware corporation with its principal place of business located at 675 North Field Drive, Lake Forest, IL 60045. TAP is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by TAP and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 83. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 83 of the Complaint.

## **Defendant Takeda Pharmaceuticals**

84. Defendant Takeda Pharmaceuticals North America, Inc. ("Takeda Pharm"), a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, is a Delaware corporation with its principal place of business located at 475 Half Day Road, Suite 500, Lincolnshire, IL, 60069. Takeda Pharm is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed,

marketed, and/or sold by Takeda Pharm and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.

84. TPNA admits that it is indirectly a wholly-owned subsidiary of Takeda Pharmaceutical Company Ltd., and that it is a Delaware corporation with its principal place of business located at 475 Half Day Road, Suite 500, Lincolnshire, IL 60069. TPNA admits that it is engaged in the business of distributing, marketing, and/or selling prescription drugs, and that some purchasers of drugs sold by TPNA are reimbursed by state Medicaid agencies. TPNA admits that the State of Alabama purports to make a claim in this litigation for the TPNA product identified in Exhibit A. Except as specifically admitted, TPNA denies the allegations set forth in Paragraph 84 of the Complaint.

#### Defendant Teva

- 85. Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), a wholly-owned American subsidiary of Teva Pharmaceutical Industries, Ltd. and formerly Lemmon Pharmaceutical Company, is a Delaware corporation with its principal place of business located at 1090 Horsham Road, P.O. Box 1090, North Wales, PA 19454-1090. Teva is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by Teva and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 85. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 85 of the Complaint.

## The Watson Defendants

- 86. Defendant Watson Pharmaceuticals, Inc ("Watson") is a Nevada corporation with its principal place of business located at 311 Bonnie Circle, Corona, CA 92880.
- 86. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 86 of the Complaint.
- 87. Defendant Watson Laboratories, Inc. ("Watson Labs"), a wholly-owned subsidiary of Watson, is a Nevada corporation with its principal place of business located at 311 Bonnie Circle, Corona, CA 92880.

- 87. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 87 of the Complaint.
- 88. Defendant Watson Pharma, Inc. ("Watson Pharma"), a wholly-owned subsidiary of Watson since 2000, is a Delaware corporation with its principal place of business located at 311 Bonnie Circle, Corona, CA 92880.
- 88. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 88 of the Complaint.
- 89. Watson, Watson Labs, and Watson Pharma (collectively, the "Watson Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Watson Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.
- 89. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 89 of the Complaint.

#### The Wyeth Defendants

- 90. Defendant Wyeth, Inc. ("Wyeth"), formerly American Home Products Corp., is a Delaware corporation with its principal place of business located at Five Giralda Farms, Madison, NJ 07940.
- 90. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 90 of the Complaint.
- 91. Defendant Wyeth Pharmaceuticals, Inc. ("Wyeth Pharm"), a division of Wyeth, is a Delaware corporation with its principal place of business located at 500 Arcola Road, Collegeville, PA 19426.
- 91. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 91 of the Complaint.
- 92. Wyeth and Wyeth Pharm (collectively, the "Wyeth Defendants") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling prescription drugs that are reimbursed by state Medicaid agencies nationwide. Pharmaceuticals that are manufactured, distributed, marketed, and/or sold by the Wyeth

Defendants and reimbursed by Alabama Medicaid for which a claim is made in this litigation are identified in Exhibit A, attached.

TPNA denies knowledge or information sufficient to form a belief as to the truth 92. of the allegations set forth in paragraph 92 of the Complaint.

#### Fictitious Defendants

- Fictitious Defendants 1 through 200, whose true names are presently 93. unknown, are manufacturers, distributors, marketers, and/or sellers of prescription drugs who reported or caused to be reported false and inflated pricing information to industry publishers upon which information the Alabama Medicaid Agency relied in reimbursing providers for the dispensing of such drugs, and whose true names will be added upon discovery.
- TPNA denies knowledge or information sufficient to form a belief as to the truth 93. of the allegations set forth in paragraph 93 of the Complaint.
- Upon information and belief, the drugs identified for each Defendant are 94. involved in the fraudulent or wanton pricing scheme outlined in this complaint. In addition to those drugs, there may be other drugs which are or have been manufactured, distributed, marketed, and/or sold by Defendants and which are subject to the fraudulent pricing scheme, but the names of those drugs are unavailable to Alabama Medicaid at the present time. For example, some of the Defendants manufacture, distribute, market, and/or sell multiple source brand name and generic drugs not listed in Exhibit A which are also manufactured by other companies. Alabama Medicaid is unable to determine without additional investigation and information which Defendants sold these multiple source brand name drugs and/or generic drugs as part of the scheme (and, if so, to what extent) for which Alabama Medicaid paid reimbursement to the provider. Likewise, Alabama Medicaid is unable to determine without additional information which Defendants sold physician-dispensed (Medicare Part B) drugs as part of the scheme for which Alabama Medicaid paid reimbursement to the provider. The State intends for this complaint to cover all drugs manufactured, distributed, marketed, and/or sold by Defendants (including Fictitious Defendants 1-200) which are subject to the fraudulent or wanton pricing scheme described herein, even though the names of some of those drugs are not identified because the information is not currently available to the State.
- TPNA denies each and every allegation set forth in paragraph 94 of the Complaint 94. as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

#### JURISDICTION AND VENUE

- 95. This Court has jurisdiction over the State's claims as they involve claims arising exclusively under Alabama law.
- 95. TPNA denies each and every allegation set forth in paragraph 95 of the Complaint.
- 96. This Court has personal jurisdiction over each Defendant either because the Defendant resides in Alabama, does business in Alabama, purposefully directs or directed its actions toward Alabama, and/or has the requisite minimum contacts with Alabama necessary to constitutionally permit the Court to exercise jurisdiction.
- 96. For purposes of this case, TPNA does not challenge the exercise of personal jurisdiction as to TPNA. As to other defendants, TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 96 of the Complaint.
- 97. Venue is proper in Montgomery County, Alabama pursuant to Alabama Code § 6-3-7, because the State pays reimbursement through Alabama Medicaid for prescription drugs dispensed in this County and throughout the State. The events giving rise to the claims herein arose, in substantial part, in this County, the State's principal office and operations are located in this County, and the State regularly and systematically conducts business in this County.
- 97. For purposes of this case, TPNA does not challenge venue in Montgomery County, Alabama. TPNA otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 97 of the Complaint.

#### FACTUAL BACKGROUND

#### The Alabama Medicaid Program

98. The Alabama Medicaid program is a state-administered program with federal matching funds which pays for medical care, including prescription drug benefits, for Alabama's low-income and disabled citizens. Alabama Medicaid currently covers approximately 900,000 individuals. Prescription drug benefits represent over 15% of Alabama Medicaid's annual budget. Since 1990, the total annual cost of pharmacy-dispensed prescription drugs to Alabama Medicaid has increased tenfold, from total annual costs of approximately \$60 million in 1990 to approximately \$600 million in 2004.

- 98. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 98 of the Complaint, except TPNA admits that the Alabama Medicaid Program is a state-administered program with federal matching funds which pays for medical care, including prescription drug benefits, for certain Alabama citizens.
- 99. Alabama Medicaid reimburses medical providers, including physicians and pharmacists, for drugs prescribed for, and dispensed to, Alabama Medicaid recipients pursuant to statutory and administrative formulas. Alabama Medicaid also pays up to the 20% co-payment for physician administered prescription drugs for Alabama Medicare beneficiaries who are qualified to receive Medicaid benefits.
- 99. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 99 of the Complaint.
- 100. Reimbursement for pharmacy-dispensed prescription drugs under the Alabama Medicaid program is based on information supplied by Defendants to industry reporting services. This information includes the following price indices: (i) Average Wholesale Price ("AWP"), which is commonly understood as the average price charged by wholesalers to retailers, such as hospitals, doctors and pharmacies, for prescription drugs, (ii) Wholesale Acquisition Cost ("WAC"), which is commonly understood as the average price paid by wholesalers to the manufacturers for prescription drugs, and (iii) on occasion (but prior to 2003), Direct Price, which is commonly understood as the price charged by drug manufacturers to non-wholesaler customers for prescription drugs. At all times relevant to this action, Defendants were aware of Alabama Medicaid's drug reimbursement formulas and procedures for pharmacy-dispensed drugs.
- 100. TPNA admits that certain price indices are reported in industry reporting sources, sometimes based on information supplied by Defendants. TPNA objects to allegations as to what was "commonly understood" as being vague and ambiguous. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 100 with regard to other Defendants. Except as stated otherwise above, TPNA denies the allegations of Paragraph 100 of the Complaint.
- 101. Medicare is a health insurance program created by the federal government for the elderly, disabled, and other eligible persons. Individuals become eligible for Medicare health insurance benefits when they turn 65 years of age or earlier if they are certified as disabled. There are two major components of the Medicare Program, Part A and Part B. Medicare Part B is an optional program that provides coverage for some

healthcare services for Alabama's participating elderly, disabled and other eligible citizens not covered by Part A. Medicare Part B pays for a portion of the cost of prescription drugs, generally those drugs which are administered by a physician provider or used with certain medical equipment.

- 101. TPNA admits the allegations set forth in paragraph 101 of the Complaint.
- 102. For prescription drugs covered by Part B, Medicare pays eighty percent (80%) of the allowable amount under federal regulations. (Until recently, the allowable amount was 95% of the national AWP for the drug.) The remaining 20% is paid by the Medicare beneficiary as a co-payment. For Alabama Medicare beneficiaries who are also qualified to receive Medicaid benefits, Alabama Medicaid pays the 20% co-payment up to the amount Alabama Medicaid would have paid if it were the only payor. At all relevant times to this action, Defendants were aware of the Alabama Medicaid's drug reimbursement formulas and procedures for Medicare Part B drugs.
- 102. TPNA denies each and every allegation set forth in paragraph 102 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein. TPNA further respectfully refers the Court to applicable state and federal laws and regulations for an explanation of Medicare reimbursement.

## The Defendants' Reporting of Inflated Pricing Information

- 103. Defendants knowingly, willfully, wantonly, and/or intentionally provided or caused to be provided false and inflated AWP, WAC, and/or Direct Price information for their drugs to various nationally known drug industry reporting services, including First DataBank (a/k/a Blue Book), Medical Economics, Inc. (a/k/a Red Book), and Medispan. These reporting services published the pricing information to various reimbursers, such as Alabama Medicaid, who have contracted to receive the information (either in electronic or hard copy form) as a basis to provide reimbursement to the medical or pharmacy providers who provide the drugs to patients.
- 103. TPNA denies each and every allegation set forth in paragraph 103 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 104. Alabama Medicaid purchased and utilized the Defendants' published AWP, WAC, and Direct Price information from First DataBank (Blue Book), and Medical Economics, Inc. (Red Book). The information from Blue Book was and is used by Alabama Medicaid with respect to reimbursement for pharmacy-dispensed drugs. As a general

matter, the information from Red Book was and is used with respect to reimbursement for Medicare Part B drug co-payments. At all relevant times to this action, Alabama Medicaid relied upon the AWP, WAC, and/or Direct Price provided by Defendants to the industry reporting services in determining the amount Alabama Medicaid reimburses providers.

- 104. TPNA denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 104 of the Complaint.
- 105. Defendants knew that the false and deceptive inflation of AWP, WAC, and/or Direct Price for their drugs would cause Alabama Medicaid to pay excessive amounts for these drugs. Defendants' inflated AWPs, WACs, and Direct Prices greatly exceeded the actual prices at which they sold their drugs to retailers (physicians, hospitals, and pharmacies) and wholesalers. Defendants' reported AWPs, WACs, and/or Direct Prices were false and misleading and bore no relation to any price, much less a wholesale or actual sales price.
- 105. TPNA denies each and every allegation set forth in paragraph 105 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 106. Defendants knowingly, willfully, wantonly, and/or intentionally concealed the true AWP, WAC, and/or Direct Price information for their respective drugs from Alabama Medicaid. Each Defendant knows its own AWP, WAC, and Direct Price which it reports to the industry reporting services for use by Medicare and the state Medicaid agencies. Each Defendant also knows whether the prices it reports to the reporting services accurately and truthfully represent the actual prices as reflected by market experience and conditions. Unless governmental or industry surveys, lawsuits, or criminal or regulatory investigations publicly reveal the true AWP, WAC, or Direct Price for a particular drug at issue, Alabama Medicaid, like other state Medicaid agencies, is not privy to the actual market prices which it can then compare against the reported prices. Defendants have concealed true market pricing information from the State for the purpose of avoiding detection of the fraudulent scheme described herein.
- 106. TPNA admits that it knows the pricing information it has reported to industry reporting sources. TPNA denies each and every other allegation set forth in paragraph 106 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 107. Defendants used undisclosed discounts, rebates and other inducements which had the effect of lowering the actual wholesale or sales prices charged to their customers as compared to the reported prices. In addition, Defendants employed secret agreements to

conceal the lowest prices charged for their pharmaceutical products. As a result of these concealed inducements, Defendants have prevented third parties, including Alabama Medicaid, from determining the true prices it charges its customers.

107. TPNA admits that some customers, including the State of Alabama, received certain discounts or rebates. Except as specifically admitted, TPNA denies each and every allegation set forth in paragraph 107 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

## Defendants' Marketing of the "Spread"

- 108. Defendants refer to the difference between the reported AWP and WAC, on the one hand, and the actual price of a drug, on the other, as the "spread" or, alternatively, "return to practice" or "return on investment." Defendants knowingly and intentionally created a "spread" on their drugs and used the "spread" to increase their sales and market share of these drugs, thereby increasing their profits. Defendants induced physicians, pharmacies, and pharmacy chain stores to purchase their drugs, rather than competitors' drugs, by persuading them that the larger "spread" on Defendants' drugs would allow the physicians and pharmacies to receive more money, and make more of a profit, through reimbursement at the expense of Alabama Medicaid.
- 108. TPNA denies each and every allegation set forth in paragraph 108 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 109. Defendants manipulated and controlled the size of the "spread" on their drugs by both increasing their reported AWPs, WACS, and Direct Prices and decreasing their actual prices to wholesalers and providers over time.
- 109. TPNA denies each and every allegation set forth in paragraph 109 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 110. In addition to manipulating the reported AWP, WAC, and/or Direct Price, Defendants used free goods, educational grants and other incentives to induce providers to purchase their drugs, all of which lowered the actual prices of the Defendants' drugs, resulting in increased profits for providers, as well as increased market share and profits of the Defendants, at the expense of Alabama Medicaid.

- 110. TPNA denies each and every allegation set forth in paragraph 110 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 111. The unfair, fraudulent, wanton, and deceptive practices engaged in by the Defendants in creating and reporting, or causing to be reported, false and inflated AWP, WAC, and/or Direct Price information for their drugs, or otherwise concealing actual pricing information, and marketing the "spread" on their drugs as an inducement to providers to utilize Defendants' drugs, has resulted in the State paying millions of dollars in excess Medicaid payments, while at the same time enriching Defendants with excessive, unjust and illegal profits.
- 111. TPNA denies each and every allegation set forth in paragraph 111 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

## Other Lawsuits, Settlements, Government Investigations, and Criminal Proceedings

- 112. The State's complaint was not drafted in a vacuum. Each family of Defendants in this case has been sued for the same or similar Medicaid drug pricing fraud scheme in one or more of at least twenty-one other states. A number of the Defendants have also been sued for related conduct in one or more of numerous pending federal actions.
- 112. TPNA denies each and every allegation set forth in paragraph 112 of the Complaint, except TPNA admits that other plaintiffs have filed complaints (only two of which even name TPNA) alleging similarly meritless and ill-informed claims, from some of which Plaintiff here appears to have largely copied its allegations.

Lawsuits have been filed in the States of Arizona, Arkansas, California, Connecticut, Florida, Illinois, Kentucky, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nevada, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Texas, West Virginia, and Wisconsin, the City of New York, and multiple New York counties.

Most of the lawsuits that assert claims for violations of federal law have been consolidated for pretrial purposes in multi-district federal litigation in Boston, Massachusetts. However, no federal claims are being asserted in this case.

- Published opinions and other public record documents generated during the course of the parallel state and federal litigation reveal that these Defendants reported fraudulent AWPs or other pricing information for selected drugs that bore no relationship whatsoever to the price at which those drugs were actually being sold to pharmacies and providers. For example, a majority of the Defendants named herein have been made the subject of an action in New York alleging a fraudulent AWP pricing scheme.3 In that suit, New York City (which pays 25% of Medicaid costs for its residents) sets forth for each of the manufacturers and drugs at issue the inflated AWP reported to industry reporting services by the Defendants and the estimated true AWP which should have been reported. Depending on the drug in question, New York City alleges that, in some instances, the reported price is over 8 times the true price. New York City's reimbursement methodology, similar to Alabama Medicaid's, is based upon AWP reported by the manufacturers to the same reporting services upon which Alabama Medicaid relies. Because the reported AWP's and, correspondingly, the true AWP's are national (not regional) in scope, New York City's experience likely parallels Alabama's and lends obvious support to the State's allegations herein. The other state lawsuits, dealing with many of the same defendants and drugs at issue in Alabama, also lend corroborative support.
- 113. TPNA denies each and every allegation set forth in paragraph 113 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- Defendants.<sup>4</sup> As part of those criminal proceedings, a number of the drug companies named in this lawsuit pled guilty to and/or agreed to settle criminal charges of having engaged in unlawful marketing and sales practices with respect to certain of their prescription drugs reimbursed under federal programs, such as Medicare, and state programs, such as Medicaid. These Defendants paid record fines and civil penalties for this admittedly wrongful conduct.
- 114. TPNA denies each and every allegation set forth in paragraph 114 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

The City of New York v. Abbott Luboratories, Inc., 04-CV-06054, in the United States District Court for the Southern District of New York (August 4, 2004).

The criminal actions include: USA, TAP Pharmaceutical Products, Inc., 1:01-cr-10354-WGY (D. Mass); USA v AstraZeneca Pharmaceuticals L.P., 1:03-cr-00055 (D. Del.); and USA v Bayer Corp., 1:03-cr-10118-RGS (D Mass.).

- The guilty pleas, settlements, and admissions of fault by the criminal defendants implicate some of the Defendants herein in what is becoming to be known as a far-reaching and widespread scheme in the pharmaceutical industry to unlawfully increase market share and profits for their products. For example, in early 2001, Bayer agreed to settle the federal criminal investigation into Bayer's marketing and sales practices with respect to KOaTE® and Kogenate®, and Bayer paid \$14 million to the federal and state governments. The Government had alleged that Bayer set and reported AWPs for the drugs at levels far higher than the actual acquisition costs of the products. Then, in 2003, Bayer agreed to plead guilty to federal criminal charges and paid fines and civil penalties totaling over \$257 million for, among other things, illegally relabeling its drugs Cipro® and Adalat CC® in order to circumvent the Medicaid Rebate Program, thus defrauding the state Medicaid programs of millions of dollars in rebate payments.
- Paragraph 115 of the Complaint appears to contain no allegations as to, or 115. relevant to, any claims against TPNA and therefore requires no answer; to the extent Plaintiff purports to make allegations as to TPNA, TPNA denies each and every allegation set forth in paragraph 115 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- In October 2001, Defendant TAP, in order to resolve federal criminal charges, agreed to plead guilty to federal criminal and civil fraud charges for, among other things, conspiring to violate the Prescription Drug Marketing Act ("PDMA") by providing free samples of Lupron® to medical providers "knowing and expecting" that these medical providers would charge patients for such free samples. TAP agreed to pay over \$875 million in fines and civil penalties to the federal government and the fifty (50) states.
- Paragraph 116 of the Complaint appears to contain no allegations as to, or 116. relevant to, any claims against TPNA and therefore requires no answer; to the extent Plaintiff purports to make allegations as to TPNA, TPNA denies each and every allegation set forth in paragraph 115 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- In June 2003, certain of the AstraZeneca Defendants agreed to plead guilty 117. to criminal charges similar to those brought against TAP. In particular, the AstraZeneca Defendants pled guilty to federal criminal and civil fraud charges for, among other things, conspiring to violate the PDMA by providing free samples of Zoladex® to medical providers "knowing and expecting" that those medical providers would charge patients for such free samples and illegally bill those free samples to state Medicaid programs. The AstraZeneca Defendants were also charged with knowingly and willfully offering and

paying illegal remuneration to physicians by marketing a "Return-to-Practice" program to induce orders to purchase Zoladex®. The Return-to-Practice program consisted of inflating the AWP used by Medicaid for reimbursement of the drug, deeply discounting the price paid by physicians for the drug, and marketing the spread between the AWP and the discounted price to physicians. The AWP was set at levels far higher than the majority of its physician customers actually paid for the drug. In resolution of these charges, the AstraZeneca Defendants paid almost \$355 million in damages and fines to the federal and state governments.

- 117. Paragraph 117 of the Complaint appears to contain no allegations as to, or relevant to, any claims against TPNA and therefore requires no answer; to the extent Plaintiff purports to make allegations as to TPNA, TPNA denies each and every allegation set forth in paragraph 117 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 118. In April 2003, GlaxoSmithKline PLC agreed to resolve a federal criminal investigation and to pay fines and civil penalties to the federal and state governments totaling more than \$87 million to resolve claims against the GSK Defendants similar to those made against the Bayer Defendants.
- 118. Paragraph 118 of the Complaint appears to contain no allegations as to, or relevant to, any claims against TPNA and therefore requires no answer; to the extent Plaintiff purports to make allegations as to TPNA, TPNA denies each and every allegation set forth in paragraph 118 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 119. In October 2002, Pfizer agreed to resolve a federal criminal investigation into its marketing and sales practices. Pfizer admitted providing unrestricted "educational grants" to customers designed to hide the true best price of Lipitor®. While this case does not involve any "best price" claims, the wrongdoing admitted by Pfizer that led to liability under federal law also provides evidence of liability under state law i.e., evidence of Pfizer's participation in the unfair and deceptive scheme in this case, including, but not limited to, evidence that Pfizer provided improper incentives and inducements to encourage sales of its products at inflated prices.
- 119. Paragraph 119 of the Complaint appears to contain no allegations as to, or relevant to, any claims against TPNA and therefore requires no answer; to the extent Plaintiff

purports to make allegations as to TPNA, TPNA denies each and every allegation set forth in paragraph 119 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

- 120. In 2004, Schering-Plough Corporation agreed to settle criminal and civil charges relating to the best price reporting of Claritin®. The Schering Plough Defendants paid \$293 million to the federal and state governments to resolve its civil and administrative liabilities.
- 120. Paragraph 120 of the Complaint appears to contain no allegations as to, or relevant to, any claims against TPNA and therefore requires no answer; to the extent Plaintiff purports to make allegations as to TPNA, TPNA denies each and every allegation set forth in paragraph 120 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 121. While a portion of the federal settlement proceeds from the above-described cases has been returned to the states, including Alabama, the State has not been compensated fully for its losses from the wrong conduct that these guilty pleas or civil settlements evidence.<sup>5</sup>
- 121. Paragraph 121 of the Complaint appears to contain no allegations as to, or relevant to, any claims against TPNA and therefore requires no answer; to the extent Plaintiff purports to make allegations as to TPNA, TPNA denies each and every allegation set forth in paragraph 121 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 122. Government investigations by Congress, the General Accounting Office ("GAO"), Health and Human Services, and the Department of Justice ("DOJ") have also revealed fraudulent drug pricing schemes by various Defendants. For example, according to Representative Pete Stark of the U.S. House Ways and Means Committee, Abbott has engaged in a price manipulation scheme through inflated representations regarding AWP and direct prices. Representative Stark has stated that: "Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to

None of the settlements described herein operate as a bar to any of the claims made in this complaint.

cause its customers to receive windfall profits from ... Medicaid ... for the express purpose of expanding sales and increasing market share ... This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting ... Medicaid claims" The U.S. Department of Justice has documented at least 81 instances in which Abbott's reported AWPs were substantially higher than the actual wholesale prices paid by wholesalers. Indeed, the federal government's investigation revealed that Abbott created spreads of more than 20,000 percent through the reporting of false and misleading average wholesale prices.

- 122. Paragraph 122 of the Complaint appears to contain no allegations as to, or relevant to, any claims against TPNA and therefore requires no answer; to the extent Plaintiff purports to make allegations as to TPNA, TPNA denies each and every allegation set forth in paragraph 122 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 123. Generic or multi-source drug manufacturers are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors' products. Generic drug manufacturers manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. The natural and expected result is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP exceeding actual costs by over 50,000%. A few examples collected by the DOJ are set forth below:

		1.0		DONABRIORIMINE	
Defendant	Yuiti-source Drug	Real	ane Avr	Actial AWDS 12	oReprentative Sincerol
Baxter*	Dextrose	\$	928.51	\$ 2.25	41,167%
Baxter*	Sodium Chloride	. \$	928.51	\$ 1.71	54,199%
Boehringer*	Leucovorin Calcium	\$	184.40	\$ 2.76	6,581%
B. Braun	Sodium Chloride	\$	11.33	\$ 1.49	660%
Bristol-Myers	Etoposide (Vepesid)	\$	136.49	\$ 34.30	298%
Group*	<u> </u>				
Dey*	Albuterol Sulfate	\$	30.25	\$ 9.17	230%
Immunex*	Leucovorin Calcium	\$	137.94	\$ 14.58	846%
Pharmacia*	Etoposide	\$	157.65	\$ 9.47	1,565%
Sicor Group	Tobramycin Sulfate	\$	342.19	\$ 6.98	4,802%
Watson*	Vancomycin HCL	\$	70.00	\$ 3.84	1,567%

#### \* Defendants herein.

123. Paragraph 123 of the Complaint appears to contain no allegations as to, or relevant to, any claims against TPNA and therefore requires no answer; to the extent Plaintiff

purports to make allegations as to TPNA, TPNA denies each and every allegation set forth in paragraph 123 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

- 124. Some of the conduct described herein goes back over 10 years prior to the filing of the original complaint in this action. As explained above, however, the nature and extent of the fraudulent scheme were not known to the State because information concerning the true prices which should have been reported to the reporting services was concealed and not publicly available. It has only been through recent regulatory investigations, criminal actions, and civil actions that the impact of the fraudulent scheme on the State has been indicated or revealed. Even today, the true market prices for many of the drugs in question for the entire time period at issue are not known by the State.
- 124. TPNA denies each and every allegation set forth in paragraph 124 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 125. Additionally, it would be impractical, if not impossible, to list in this Complaint, for the entire time period that the inflated pricing scheme has been in effect, the true market price as compared to the reported price for each drug in question. It is not unusual for a drug manufacturer to report fluctuating prices for a particular drug on multiple occasions within a particular year, month, week, or even day. To display pricing reports for all of the Defendants and all of the drugs in question over a ten-year-plus period would be a massive undertaking, and limitations of time and space do not permit that information, even if it were available, to be set forth in this pleading.
- 125. TPNA objects to the term "true market price" as vague and ambiguous. TPNA denies each and every allegation set forth in paragraph 125 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and affirmatively states that if there were any merit to the claims alleged herein as to TPNA, it would neither be impractical nor impossible for the Plaintiff to allege specifically its claims as to TPNA, which Plaintiff has entirely failed to do.
- 126. For purposes of specificity of pleading (particularly with respect to the fraud allegations), suffice it to say that Defendants are and have been on notice of the claims asserted herein as a result of the many investigations and actions undertaken around the country on this same subject. Indeed, each Defendant should know without further

allegation from the State exactly how its reported prices compare to its true prices and whether it has engaged in an inflated pricing scheme regarding prescription drugs.

TPNA denies each and every allegation set forth in paragraph 126 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

#### **CLAIMS**

## COUNT ONE -FRAUDULENT MISREPRESENTATION

- The State hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.
- TPNA repeats and incorporates by reference its responses to numbered 127. paragraphs 1 through 126 above.
- 128. Defendants committed fraud against the State and its agency, Alabama Medicaid. Defendants reported or caused to be reported AWP, WAC, and Direct Price for their products on a periodic and continuing basis for publication and dissemination to state Medicaid agencies such as Alabama Medicaid. Defendants knew that the AWP, WAC, and Direct Price information which they provided and caused to be reported was false. Defendants misrepresented the pricing information with the intent of inducing Alabama Medicaid to rely on the false information in setting prescription drug reimbursement rates. Alabama Medicaid reasonably relied on the false pricing data in setting prescription drug reimbursement rates and making payment based on said rates. Defendants' misrepresentations are continuing, as they regularly and periodically continue to issue false and inflated AWP, WAC, and Direct Price information for publication by the industry reporting services. As a result of Defendants' fraudulent conduct, the State has been damaged by paying grossly excessive amounts for Defendants' prescription drugs.
- TPNA denies each and every allegation set forth in paragraph 128 of the 128. Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, except TPNA admits that from time to time during the relevant period, TPNA provided certain pricing information to third party publications.
- By engaging in the acts and practices described above, the Defendants have engaged and continue to engage in repeated fraudulent acts and practices in violation of Alabama common law and Section 6-5-101 of the Alabama Code.

- 129. TPNA denies each and every allegation set forth in paragraph 129 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 130. Defendants' conduct was and is knowing, intentional, gross, oppressive, malicious, wanton, and/or committed with the intention to cause injury.
- 130. TPNA denies each and every allegation set forth in paragraph 130 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

## COUNT TWO - FRAUDULENT SUPPRESSION

- 131. The State hereby repeats, incorporates by reference and re-alleges each and every allegation set forth above in this Complaint.
- 131. TPNA repeats and incorporates by reference its responses to paragraphs 1 through 130 above.
  - 132-139. [There are no paragraphs 132-139 in the Complaint.]
- 140. Defendants committed fraud against the State and its agency, Alabama Medicaid. Defendants voluntarily undertook to report or cause to be reported AWP, WAC, and Direct Price for their products on a periodic and continuing basis for publication and dissemination to state Medicaid agencies including Alabama Medicaid. Defendants knew that the AWP, WAC, and Direct Price information which they provided and/or caused to be reported was false, incomplete and/or outdated and Defendants suppressed and concealed facts within their knowledge which would have materially qualified the reported prices. Defendants had a duty under the particular circumstances to provide accurate and complete AWP, WAC, and Direct Price information. By controlling the AWP, WAC, and Direct Price information for covered drugs which is reported to and through the publishers, Defendants concealed and suppressed their fraudulent conduct from Alabama Medicaid. Defendants knew that the AWP, WAC, and Direct Price information which they concealed or failed to disclose and/or update would induce Alabama Medicaid to rely on false pricing information in setting prescription drug reimbursement rates. Alabama Medicaid was in fact induced to rely on the false pricing data in setting prescription drug reimbursement rates and made payments based on said rates. Alabama Medicaid could not have reasonably discovered the fraudulent nature of the published AWP, WAC, and Direct Price information, as Defendants took active steps to conceal true market pricing information and to avoid detection of the fraudulent pricing

scheme. Defendants' suppression and concealment of information was continuing, as they regularly and periodically continued to conceal material information regarding inflated AWP, WAC, and Direct Price information submitted by Defendants for publication by the industry reporting services. As a result of Defendants' fraudulent conduct, the State has been damaged by paying grossly excessive amounts for Defendants' prescription drugs.

- 140. TPNA denies each and every allegation set forth in paragraph 140 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, except TPNA admits that from time to time during the relevant period, TPNA provided certain pricing information to third party publications.
- 141. By engaging in the acts and practices described above, the Defendants have engaged and continue to engage in repeated fraudulent suppression and concealment in violation of Alabama common law and Section 6-5-102 of the Alabama Code.
- 141. TPNA denies each and every allegation set forth in paragraph 141 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 142. Defendants' conduct was and is knowing, intentional, gross, oppressive, malicious, wanton, and/or committed with the intention to cause injury.
- 142. TPNA denies each and every allegation set forth in paragraph 142 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

## **COUNT THREE - WANTONNESS**

- 143. The State hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.
- 143. TPNA repeats and incorporates by reference its responses to paragraphs 1 through 142 above.
- 144. With reckless indifference to the consequences, Defendants consciously reported false and inflated pricing information, including AWP, WAC, and Direct Price,

while knowing of the falsities and being conscious that, from reporting such false and inflated pricing information, injury would likely or probably result.

- TPNA denies each and every allegation set forth in paragraph 144 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 145. Defendants' actions did, in fact, injure the State, and specifically Alabama Medicaid, by causing Alabama Medicaid to pay grossly excessive amounts for Defendants' prescription drugs.
- TPNA denies each and every allegation set forth in paragraph 145 of the 145. Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- By engaging in such actions and practices, the Defendants have engaged and continue to engage in repeated wanton acts and practices in violation of Alabama common law.
- TPNA denies each and every allegation set forth in paragraph 146 of the 146. Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- Defendants' conduct was and is knowing, intentional, gross, oppressive, malicious, fraudulent, and/or committed with the intention to cause injury.
- TPNA denies each and every allegation set forth in paragraph 147 of the 147. Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

### COUNT FOUR -UNJUST ENRICHMENT

- The State hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.
- TPNA repeats and incorporates by reference its responses to numbered 148. paragraphs 1 through 147 above.

- 149. As a result of the false and misleading statements and representations regarding drug prices contained in each Defendant's reporting of AWP, WAC, and Direct Price, Alabama Medicaid has paid excessive amounts in connection with purchases or reimbursements of purchases of Defendants' prescription drugs.
- 149. TPNA denies each and every allegation set forth in paragraph 149 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 150. Defendants knew that medical providers, including pharmacies and physicians, who obtained Medicaid reimbursement for Defendants' drug products were not entitled to improperly inflated reimbursement rates that were based on Defendants' false AWPs, WACs, and Direct Prices.
- 150. TPNA denies each and every allegation set forth in paragraph 150 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 151. As a result of the excessive payments to providers by Alabama Medicaid of all or part of the "spread," Defendants obtained increased sales and market share for their products, and, therefore, increased profits, and were unjustly enriched at the expense of the State and Alabama Medicaid.
- 151. TPNA denies each and every allegation set forth in paragraph 151 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 152. Defendants knew they were not entitled to the profits that resulted from the sales obtained through the use of the spreads they created, and Defendants should be required to account for and make restitution to the State of all such amounts obtained through the use of such spreads.
- 152. TPNA denies each and every allegation set forth in paragraph 152 of the Complaint as to TPNA, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

TPNA further denies that plaintiffs are entitled to a judgment or any other relief requested in their section entitled "PRAYER FOR RELIEF" and unnumbered "WHEREFORE" paragraph following paragraph 152 of the Complaint.

# TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.'S AFFIRMATIVE DEFENSES

By alleging the matters set forth below, TPNA does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters or that plaintiff is relieved of its burdens to prove each and every element of its claims and the damages, if any, to which it is entitled. As and for its affirmative defenses, TPNA alleges as follows:

## FIRST AFFIRMATIVE DEFENSE

153. Plaintiff fails to state a claim against TPNA upon which relief may be granted.

## SECOND AFFIRMATIVE DEFENSE

154. Plaintiff has failed to plead fraud with the requisite specificity.

## THIRD AFFIRMATIVE DEFENSE

155. Plaintiff's claims are barred, in whole or in part, because plaintiff has not reasonably relied on any allegedly fraudulent representations made by TPNA.

## FOURTH AFFIRMATIVE DEFENSE

156. Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

#### <u>FIFTH AFFIRMATIVE DEFENSE</u>

157. Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit to recover Medicaid expenditures or to seek injunctive relief.

#### SIXTH AFFIRMATIVE DEFENSE

158. Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of TPNA as alleged in the Complaint.

## SEVENTH AFFIRMATIVE DEFENSE

159. To the extent plaintiff's claims would result in TPNA paying damages to more than one claimant for the same alleged overcharge, they are barred because such multiple liability would violate rights guaranteed to TPNA by the United States Constitution, including, without limitation, rights guaranteed under the Due Process Clause of the Fourteenth Amendment.

#### EIGHTH AFFIRMATIVE DEFENSE

160. To the extent plaintiff obtains recovery in any other case predicated on the same factual allegations, plaintiff is barred from seeking recovery against TPNA based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

#### NINTH AFFIRMATIVE DEFENSE

161. Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Alabama.

#### TENTH AFFIRMATIVE DEFENSE

162. Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

#### ELEVENTH AFFIRMATIVE DEFENSE

163. Plaintiff's claims are barred, in whole or in part, to the extent that plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

### TWELFTH AFFIRMATIVE DEFENSE

164. Any and all actions taken by TPNA with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

## THIRTEENTH AFFIRMATIVE DEFENSE

165. Plaintiff's claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

## FOURTEENTH AFFIRMATIVE DEFENSE

166. Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

#### FIFTEENTH AFFIRMATIVE DEFENSE

167. Plaintiff's claims against TPNA are barred because TPNA has complied with all applicable regulations of the federal and state governments.

#### SIXTEENTH AFFIRMATIVE DEFENSE

168. Plaintiff's claims against TPNA are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

#### SEVENTEENTH AFFIRMATIVE DEFENSE

169. Plaintiff's claims are barred, in whole or in part, because they violate TPNA's rights under the Due Process and Ex Post Facto clauses of the United States Constitution, as well as the Constitution of the State of Alabama, insofar as plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

### EIGHTEENTH AFFIRMATIVE DEFENSE

170. TPNA's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by plaintiff.

## NINETEENTH AFFIRMATIVE DEFENSE

171. To the extent that plaintiff attempts to seek equitable relief against TPNA, it is not entitled to such relief because it has an adequate remedy at law.

## TWENTIETH AFFIRMATIVE DEFENSE

172. Plaintiff's claims against TPNA for injunctive relief were mooted by the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

#### TWENTY-FIRST AFFIRMATIVE DEFENSE

173. Plaintiff's claims for injunctive relief against TPNA are barred by the doctrines of in pari delicto and/or unclean hands.

## TWENTY-SECOND AFFIRMATIVE DEFENSE

174. Plaintiff's claims against TPNA are barred, in whole or in part, due to its failure to join indispensable parties.

#### TWENTY-THIRD AFFIRMATIVE DEFENSE

175. Plaintiff's claims against TPNA are barred, in whole or in part, because it has suffered no damages as a result of the matters alleged in the Complaint.

#### TWENTY-FOURTH AFFIRMATIVE DEFENSE

176. Plaintiff's claims are barred, in whole or in part, because any injuries sustained by plaintiff were the result of its own conduct or the intervening or superceding conduct of third parties.

## TWENTY-FIFTH AFFIRMATIVE DEFENSE

because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery of plaintiff and the allocation of any fault, if any exists, attributable to TPNA; (2) because it would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that plaintiff has paid for products distributed, marketed or sold by TPNA after the filing of plaintiff's original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

### TWENTY-SIXTH AFFIRMATIVE DEFENSE

178. TPNA is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by plaintiff, with respect to the same alleged injuries.

## TWENTY-SEVENTH AFFIRMATIVE DEFENSE

179. Any damages recovered by the plaintiff from TPNA must be limited by the applicable statutory ceilings on recoverable damages, including without limitation, Alabama Code § 6-11-21.

## TWENTY-EIGHTH AFFIRMATIVE DEFENSE

180. Plaintiff fails to allege facts or a cause of action against TPNA sufficient to support a claim for compensatory damages, attorneys' fees and/or legal fees, or any other relief.

### TWENTY-NINTH AFFIRMATIVE DEFENSE

181. To the extent punitive damages are sought, Plaintiff's punitive damages claims against TPNA: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against TPNA; (3)

cannot be sustained because the laws regarding the standards for determining liability for and the amount of punitive damages fail to give TPNA prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of TPNA's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Alabama; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws of Alabama or other comparable laws would violate TPNA's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and laws of the State of Alabama; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against TPNA for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of TPNA's products would constitute impermissible multiple punishments for the same wrong, in violation of TPNA's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law, and statutory laws of the State of Alabama; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate TPNA's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Alabama; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according TPNA the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate TPNA's rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Alabama.

### THIRTIETH AFFIRMATIVE DEFENSE

To the extent punitive damages are sought, Plaintiff's claims for punitive damages 182. against TPNA cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of TPNA; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate TPNA's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law, and public policies of the State of Alabama.

## THIRTY-FIRST AFFIRMATIVE DEFENSE

183. To the extent punitive damages are sought, Plaintiff's claims for punitive damages against TPNA cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate TPNA's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate TPNA's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law, and public policies of the State of Alabama.

## THIRTY-SECOND AFFIRMATIVE DEFENSE

184. Plaintiffs are estopped from claiming to have been defrauded by virtue of any action by TPNA in light of disclosures and disclaimers accompanying pricing information TPNA supplied to industry reporting sources.

## THIRTY-THIRD AFFIRMATIVE DEFENSE

185. Some or all of plaintiff's claims against TPNA arise from plaintiff's failure to follow its federal and state statutory and regulatory obligations to properly establish appropriate reimbursement rates.

## THIRTY-FOURTH AFFIRMATIVE DEFENSE

186. Plaintiff's unjust enrichment claims are barred, in whole or in part, because TPNA did not retain any money belonging to the State as a result of any alleged overpayments as required under Alabama law.

# THIRTY-FIFTH AFFIRMATIVE DEFENSE

187. Plaintiff's claims against TPNA are misjoined with plaintiff's claims against other defendants and must be severed.

## THIRTY-SIXTH AFFIRMATIVE DEFENSE

188. TPNA adopts and incorporates herein any and all answers and defenses pled by any other defendant which are applicable to TPNA.

# THIRTY-SEVENTH AFFIRMATIVE DEFENSE

189. TPNA hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

WHEREFORE, defendant Takeda Pharmaceuticals North America, Inc. demands that:

(1) the Complaint be in all respects dismissed as to it; (2) it be awarded its costs of defending this action, including its reasonable attorneys' fees; and (3) it be awarded such other and further relief as the Court may deem just and proper.

Dated the 30th day of January, 2006

Respectfully submitted,

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Inc.

## CERTIFICATE OF SERVICE

I hereby certify that I have on this 30<sup>th</sup> day of January, 2006, electronically served a true and correct copy of the foregoing pleading on counsel of record by transmission to LNFS pursuant to Case Management Order No. 2.

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